



UK stillbirth trends in over 11 million births provide no evidence to support effectiveness of Growth Assessment Protocol program

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CONTRIBUTION

What are the novel findings of this work?

The recent reduction in stillbirths in England and Wales cannot be attributed solely to the introduction of the Growth Assessment Protocol (GAP) program. The greater decline in the stillbirth rate in Scotland, despite the low uptake of the program, suggests that other beneficial public health measures common to both systems are responsible.

What are the clinical implications of this work?

Further implementation of the GAP program and use of customized growth centiles is not warranted on the basis of our findings.

ABSTRACT

Objective Use of the Growth Assessment Protocol (GAP) has increased internationally under the assumption that it reduces the stillbirth rate. The evidence for this is limited and based largely on an ecological time-trend study. Discordance in the uptake of the GAP program between Scotland and England/Wales enabled us to assess the assertion that implementation of GAP leads to a reduced stillbirth rate.

Methods We analyzed data from the National Records for Scotland and the Office for National Statistics on the number of singleton maternities and stillbirths in Scotland and in England and Wales, respectively, from 1 January 2000 to 31 December 2015. National uptake of the GAP program over time in each of the regions was recorded. Stillbirth rate per 1000 maternities was calculated, according to year of delivery, and compared between Scotland and England/Wales.

Results During the study period, there were 870 632 singleton maternities in Scotland, of which 4243 were stillbirths, and there were 10 469 120 singleton maternities in England and Wales, of which 51 562 were stillbirths. There was a marked difference in uptake of the GAP program between the two regions, with substantially fewer maternity units in Scotland implementing the program. Stillbirth rates were static up to 2010, with a decline thereafter in both regions, to 3.75 (95% CI, 3.25–4.30) per 1000 maternities in Scotland and 4.30 (95% CI, 4.15–4.46) per 1000 maternities in England and Wales in 2015. From 2010 onwards, the decline in Scotland was faster, equating to 48 (95% CI, 47.9–48.1) fewer stillbirths per 100 000 maternities in Scotland than in England and Wales from 2010 to 2015 compared with 2000 to 2009.

Conclusions We observed a decline in stillbirth rate in England and Wales, which coincided with implementation of the GAP program. However, a concurrent decline in stillbirth rate was observed in Scotland in the absence of increased implementation of GAP. The secular rates of change in stillbirth rate in England and Wales cannot be used to infer efficacy of the GAP program. © 2020 The Authors. *Ultrasound in Obstetrics & Gynecology* published by John Wiley & Sons Ltd on behalf of the International Society of Ultrasound in Obstetrics and Gynecology.

INTRODUCTION

There are marked disparities in stillbirth rates across high-income countries, which likely reflects underlying differences in risk factors between countries, but could

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also reflect variation in care, such as detecting and monitoring fetal growth restriction (FGR), one of the major causes of stillbirth¹. Screening for FGR in low-risk women in many countries is through clinical assessment, measuring symphyseal–fundal height, followed by targeted use of ultrasonographic fetal biometry. A refinement in the standard approach to FGR screening is to account for the mother's characteristics, so-called customization, in which the calculated weight centile is adjusted for maternal age, weight, height, parity and ethnicity, as well as with the conventional adjustment for gestational age and fetal sex². In the UK, the promotion of customized centiles has been through a package of care known as the Growth Assessment Protocol (GAP) which trains midwives and healthcare professionals in fetal growth assessment and the use of customized centiles.

There is no robust evidence that implementation of GAP and use of customized fetal growth charts reduce stillbirth and, on the basis of this, they were pointedly not recommended in the most recent National Institute for Health and Care Excellence (NICE) guidelines on antenatal care, with specific recommendation for further prospective studies assessing their efficacy³. Despite this, proponents of the program claim that GAP, along with customized growth charts, reduce stillbirth rates through more accurate identification of those with FGR^{4,5}. One of the key pieces of evidence advanced to support their adoption was an apparent decline in stillbirth rate in England and Wales, which coincided with increasing implementation of the GAP program^{5,6}. The results of such ecological studies need to be interpreted cautiously. These well publicized, but not evidence-based, claims have led to widespread adoption of customized growth charts and weight centiles by many maternity units in England and Wales and globally, including in Australia, Europe, New Zealand and the USA⁶.

The aim of this study was to compare the recent temporal trends in stillbirth rate in England and Wales with those in Scotland. The rationale for this approach is that widespread implementation of the GAP program in England and Wales predated any implementation in Scotland. However, the health services are otherwise very similar between the two areas. Therefore, comparing these geographical territories can help test the plausibility of the assertion that the increased implementation of the GAP program in England and Wales led to a reduced rate of stillbirth in those countries. Clarification of whether there is a directly attributable beneficial effect is critical, as adoption of the GAP program by many other countries is ongoing in the belief that its use prevents stillbirth.

METHODS

Data collection

National Records for Scotland and the Office for National Statistics provided information on the numbers of stillbirths and maternities in Scotland and in England and Wales, respectively, from 1 January 2000 to

31 December 2015 inclusive. Multiple pregnancy was excluded. Additional data stratified by maternal age were provided for both regions. Information on the number of stillbirths attributed to congenital or chromosomal abnormalities was collated for Scotland. No ethical approval was required for this study.

We assessed uptake of the GAP program in Scotland using a survey of the lead obstetrician and/or obstetric sonographer in all maternity units. This was done using a brief structured questionnaire that asked for information on the timing and extent of uptake of the protocol between January 2000 and December 2015. This questionnaire was administered via telephone by the first author. Uptake in England and Wales was assessed using published information^{5,7}.

Data analysis

Crude stillbirth rate was defined as the number of singleton stillbirths per 1000 singleton maternities. Standardized stillbirth rate was derived from direct standardization for maternal age to account for differences in maternal age distribution between the two regions. Stillbirth rates (crude and standardized) with 95% CI were plotted against year of delivery. On visual inspection of the time trends, there was an evident decline in stillbirth rate. We then compared, by fitting a linear regression model for year and region, the difference in aggregate age-standardized stillbirth rate before and after the visual decline, respectively, between the two populations. We also calculated the absolute difference with 95% CI in crude stillbirth rate between the two populations per year and estimated the difference in the absolute number of stillbirths per 100 000 maternities, before and after the decline, between Scotland and England/Wales.

RESULTS

Between 1 January 2000 and 31 December 2015, there were 10 469 120 singleton maternities in England and Wales, of which 51 562 were stillbirths, and there were 870 632 singleton maternities in Scotland, of which 4243 were stillbirths. All 15 maternity units in Scotland responded to our survey about the use of the GAP program. Figure 1 compares data from the survey in Scotland with those for England and Wales obtained from published information^{5,7}. There was a marked difference in use of the GAP program for most of the study period, with just one (7%) unit in Scotland implementing it between 2000 and the start of 2015, compared with a steady increase in England and Wales to 97 (68%) units by the start of 2015. During 2015, a further five Scottish units commenced using the GAP program; by the end of the final year of our study period, 40% of Scottish units, compared with 72% of those in England and Wales, were using the GAP program.

Figure 2 and Table 1 show crude stillbirth rates with 95% CI for singleton maternities in England and Wales and in Scotland, according to year of delivery, from

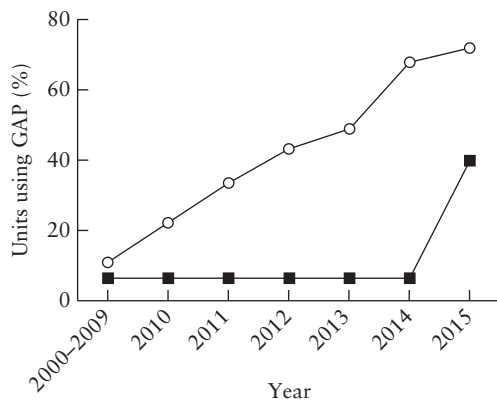


Figure 1 Percentage uptake of Growth Assessment Protocol (GAP) program in maternity units in Scotland (■) and in England and Wales (○), from 2000 to 2015.

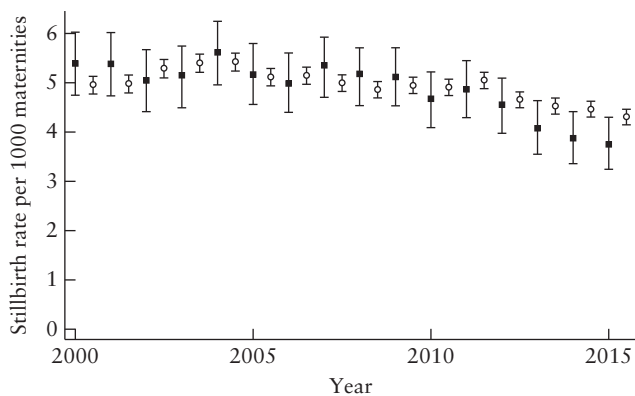


Figure 2 Crude stillbirth rate with 95% CI in Scotland (■) and in England and Wales (○), according to year of delivery, from 2000 to 2015.

2000 to 2015. Figure 3 and Table 1 show the equivalent age-standardized stillbirth rates, which do not differ substantially from the crude rates. In both regions, the rates were static up to 2010 with a decline thereafter. The lowest rates were observed in 2015 (4.30 (95% CI, 4.15–4.46) per 1000 maternities in England and Wales and 3.75 (95% CI, 3.25–4.30) per 1000 maternities in Scotland). From 2000 to 2009, the rates were comparable between Scotland and England/Wales (mean difference, 0.12 (95% CI, –0.06 to 0.30); $P=0.17$). From 2010 onwards, the decline in stillbirth rate in Scotland was faster than that in England and Wales (mean difference, –0.36 (95% CI, –0.58 to –0.14); $P=0.005$), equating to 48 (95% CI, 47.9–48.1) fewer stillbirths per 100 000 maternities in Scotland than in England and Wales in 2010 to 2015, compared with in 2000 to 2009. Figure S1 shows that the percentage of stillbirths attributed to

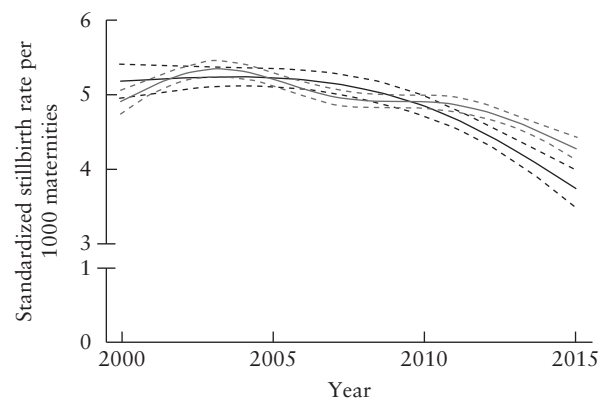


Figure 3 Maternal-age standardized stillbirth rate (solid lines) and 95% CI (dashed lines) in Scotland (black) and in England and Wales (gray), according to year of delivery, from 2000 to 2015.

Table 1 Number of singleton maternities, stillbirths and stillbirth rate per 1000 maternities in Scotland and in England and Wales, according to year of delivery, from 2000 to 2015

Year	Scotland				England and Wales				Difference*
	Mater- nities	Still- births	Stillbirth rate		Mater- nities	Still- births	Stillbirth rate		
			Crude	MA standardized			Crude	MA standardized	
2000	51 840	279	5.38 (4.75–6.03)	5.18 (4.95–5.41)	589 788	2920	4.95 (4.77–5.13)	4.91 (4.75–5.07)	0.43 (–0.20 to 1.06)
2001	51 224	275	5.37 (4.74–6.02)	5.20 (5.02–5.39)	580 168	2887	4.98 (4.80–5.16)	5.11 (5.01–5.22)	0.33 (–0.25 to 1.03)
2002	50 032	252	5.04 (4.42–5.68)	5.22 (5.07–5.38)	581 592	3074	5.29 (5.10–5.48)	5.27 (5.18–5.37)	–0.25 (–0.91 to 0.41)
2003	51 079	263	5.15 (4.56–5.80)	5.24 (5.11–5.37)	606 683	3273	5.39 (5.21–5.58)	5.35 (5.24–5.46)	–0.25 (–0.91 to 0.41)
2004	52 732	296	5.61 (4.96–6.25)	5.24 (5.12–5.36)	624 207	3383	5.42 (5.24–5.60)	5.32 (5.22–5.42)	0.19 (–0.85 to 0.46)
2005	52 968	273	5.15 (4.56–5.80)	5.23 (5.11–5.35)	630 084	3222	5.11 (4.94–5.29)	5.21 (5.12–5.30)	0.04 (–0.59 to 0.67)
2006	54 240	270	4.98 (4.40–5.61)	5.20 (5.07–5.33)	652 778	3357	5.14 (4.97–5.32)	5.08 (4.98–5.17)	–0.16 (–0.79 to 0.46)
2007	56 303	301	5.35 (4.71–5.93)	5.15 (5.01–5.29)	672 528	3358	4.99 (4.83–5.16)	4.97 (4.86–5.07)	0.31 (–0.25 to 0.96)
2008	58 427	302	5.17 (4.54–5.71)	5.08 (4.94–5.22)	690 442	3355	4.86 (4.70–5.03)	4.92 (4.82–5.02)	0.31 (–0.27 to 0.90)
2009	57 471	294	5.12 (4.53–5.71)	4.98 (4.84–5.12)	686 870	3399	4.95 (4.78–5.12)	4.91 (4.83–5.00)	0.17 (–0.43 to 0.77)
2010	57 204	267	4.67 (4.09–5.22)	4.85 (4.71–4.99)	704 240	3455	4.91 (4.74–5.07)	4.91 (4.82–5.00)	–0.24 (–0.83 to 0.36)
2011	57 153	278	4.86 (4.29–5.45)	4.68 (4.55–4.81)	704 535	3556	5.05 (4.88–5.22)	4.87 (4.77–4.97)	–0.18 (–0.79 to 0.42)
2012	56 541	257	4.55 (3.97–5.10)	4.48 (4.35–4.61)	710 133	3304	4.65 (4.50–4.81)	4.78 (4.68–4.88)	–0.11 (–0.69 to 0.48)
2013	54 569	222	4.07 (3.55–4.64)	4.25 (4.10–4.40)	680 037	3078	4.53 (4.37–4.69)	4.64 (4.56–4.73)	–0.46 (–0.10 to 0.13)
2014	55 194	213	3.86 (3.36–4.41)	4.01 (3.81–4.20)	676 357	3020	4.47 (4.31–4.63)	4.47 (4.37–4.57)	–0.61 (–1.18 to –0.03)
2015	53 655	201	3.75 (3.25–4.30)	3.75 (3.50–4.00)	678 678	2921	4.30 (4.15–4.46)	4.28 (4.13–4.44)	–0.56 (–1.13 to 0.02)

Data are given as *n* or rate per 1000 maternities (95% CI). *Crude stillbirth rate in Scotland compared to in England and Wales (reference). MA, maternal-age.

congenital or chromosomal abnormality in Scotland increased marginally over the study period (P -value for trend = 0.05).

When we removed data from 2015 (i.e. when there was an increase in the number of units adopting the GAP program in Scotland), the results were essentially unchanged, with 41 (95% CI, 40.9–41.1) fewer stillbirths per 100 000 maternities in Scotland than in England and Wales in 2010 to 2014, compared with in 2000 to 2009. However, there was no significant trend in the number of stillbirths attributed to congenital or chromosomal abnormality in Scotland from 2000 to 2014 (P -value for trend = 0.34).

DISCUSSION

The main finding of this study is that the stillbirth rate declined both in Scotland and in England and Wales between 2010 and 2015, despite the discrepancy in implementation of the GAP program between the regions. Previous studies analyzing the rate of stillbirth in England and Wales interpreted the decline in rate as being potentially attributable to the increasing implementation of the GAP program because of their concurrence⁵; this has been used widely to promote GAP^{4,5}. However, our current observations do not support this interpretation, as there was no increase in implementation of the GAP program in Scotland over the same period. Given the close similarities between the healthcare systems, it seems likely that some common factors would have led to the fall in stillbirth rate in the two regions. As increased implementation of the GAP program was not common to both regions, this cannot plausibly explain the decline.

Why might stillbirth rates be declining across the UK?

The stillbirth rate reflects a population's quality of maternity care and women's health⁸. Therefore, the declining trends both in England and Wales and in Scotland, for the first time over the last 16 years, must coincide with contemporary advances in UK antenatal practice and/or factors related to improved maternal health. The publication of comprehensive NICE guidance in 2008 and the implementation of its recommendation for routine care in pregnancy may have contributed³. The Lancet's Stillbirth Series, published in 2011, summarized strategies that could lead to a reduction in stillbirth rate in both low- and high-income countries^{8–10}. The smoking cessation policy, which was adopted throughout the UK in 2006 and 2007^{11,12}, may have contributed to the recent reduction in stillbirth rate across the UK, including Scotland. The more marked decline in Scotland, compared with in England and Wales, as a result of these interventions may be, for example, due to the greater absolute decline in smoking rate in Scotland following the cessation policy^{13,14} or the greater absolute increase in the uptake of antenatal care in the first trimester in Scotland compared to in England (from 65% in 2011

to 82% in 2015 *vs* 89% in 2010 to 92% in 2015)¹⁵. The liberal use of third-trimester ultrasound along with Doppler studies may have been a contributing factor to the overall declining stillbirth rate^{16–18}.

Why might the GAP program fail to influence stillbirth rates?

A central component of the GAP program is the use of customized fetal growth charts, but their key assumption that a smaller fetus is related to variations in maternal age, parity, weight, height and ethnicity and is physiological rather than pathological, and therefore not at increased risk for stillbirth, may be incorrect. We have shown previously that partial customization weakened the association between birth-weight centile and the risk of perinatal death at term¹⁹. Other large cohort studies have demonstrated that customized birth-weight centiles do not improve prediction of term stillbirth, as compared with population-based birth-weight standards^{20,21}. Studies that have supported the use of customized birth-weight centiles have included both preterm and term births^{22,23}, with current evidence suggesting that gestational age may modify the associations²⁴.

Further evidence and comparison with other studies

Assessment of the direct effect of adoption of the GAP program has been limited⁶. An interinstitutional comparison between English maternity units with high uptake of the GAP program and those with low uptake demonstrated a greater decline (~8%) in stillbirth rate in the former from 2007 to 2012⁴. However, that the stillbirth rate was initially greater in the high-uptake regions than the national average or that in the low uptake regions, suggests that the subsequent decline to national average rates may have been due to standardization of antenatal care or regression to the mean.

To date, there has been only one small controlled trial of the GAP program, which demonstrated that the method identified an additional 20% of small-for-gestational-age cases, as compared with symphyseal–fundal height measurement²⁵, without evidence of differences in perinatal outcome, including stillbirth, between the two groups. Hence, NICE did not recommend GAP in their antenatal care guideline. Assuming a high background risk of stillbirth of 5 in 1000 maternities, we calculated that a randomized controlled trial (RCT) comparing the GAP program to current standardized care would require more than 2.4 million women to be randomized to confirm a minimal difference of 5% in stillbirth rate.

Strengths and limitations

This study used population data with 100% coverage from two groups (covering three countries) with a marked difference in uptake of the GAP program, but very similar healthcare provision. We acknowledge that an ecological study cannot infer causality at an individual level, nor

can it take into account all the additional discrepancies between the two populations that may contribute to the disparity in the outcome of interest. However, our research objective was not to assess causality. The antenatal populations across England/Wales and Scotland are broadly similar with respect to maternal age and socioeconomic position^{26,27}. We limited our analysis to singleton pregnancy in accordance with the use of the GAP program² and we examined the trend in stillbirth rate over a long time period to allow for a lag between uptake of the GAP program and any possible impact on stillbirth rate. We did not undertake a survey of maternity units in England and Wales as we did in Scotland, but we used published data^{5,7}. That the rate of stillbirths attributable to congenital or chromosomal abnormality had not altered substantially in Scotland, at least until 2014, suggests that the observed reduction in stillbirth rate is not attributable to the later introduction of routine fetal anomaly ultrasound and termination of affected pregnancies.

Future research

The declining trend in stillbirth rate is promising; however, the UK still has one of the highest rates among high-income countries. Developing efficient and accurate strategies to identify fetuses at risk of stillbirth, and that will benefit from early delivery, is a key priority²⁸. Our sample size calculations suggest that a prohibitively large sample size would be required for a RCT of the GAP program *vs* standard care²⁹. Novel approaches to experimental studies, such as stepped-wedge RCTs, can be conducted to address the impact of other interventions, with stillbirth as a primary outcome^{30,31}.

Conclusion

Stillbirth rates in England and Wales and in Scotland have been declining since 2010. Our findings suggest that this trend in England and Wales cannot be attributed reliably to implementation of the GAP program, since the decline has not been greater than that in Scotland, in which the uptake of GAP was low. Implementation of the GAP program cannot be justified based on ecological studies of the stillbirth rate in England and Wales.

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SUPPORTING INFORMATION ON THE INTERNET

The following supporting information may be found in the online version of this article:



Figure S1 Percentage of stillbirths (95% CI) attributed to congenital or chromosomal abnormality in Scotland, according to year of delivery, from 2000 to 2015.